Abstracts for the 2000 FDA science forum from the OST reuse-mob.

Effects of Use and Reprocessing on Single Use Coronary Catheters. S. A. Brown[1], K. Merritt[2], V. M. Hitchins[2], and T. O. Woods[1]. [1]*Division of Mechanics and Materials Science and* [2]*Division of Life Sciences, CDRH/ FDA, Rockville Md-20852.*

Although sold for single use only, some medical devices, such as coronary catheters, are being processed for reuse. Over 400 PTCA and 300 EP catheters have been retrieved after single patient use at Walter Reed Army Hospital. After disinfection and cleaning, a variety of performance characteristics were determined, and then some were subjected to ETO sterilization and simulated reuse. The results demonstrated that cleaning was not a trivial problem. The balloon compliance data demonstrated model specific changes. Some catheters became more sticky making insertion more difficult. Some models of EP's were non-lumen, whereas others had hollow cores sometimes contaminated with blood. Damage to electrode seals exposed the lumens as well as copper wires connected to the electrodes. Unbeknownst to the user, subtle changes in device appearance may be associated with major changes in the performance of a used or reused device.

Effects of Different Sterilization Methods on Materials Used for Single Use Devices (SUDs) S. A. Brown[1], K. Merritt[2], T. O. Woods[1],and V. M. Hitchins[2]. [1]*Division of Mechanics and Materials Science and* [2]*Division of Life Sciences, CDRH/ FDA, Rockville Md-20852*

Driven by economic and time constraints, some medical centers and third parties are resterilizing SUDs for reuse. The steam autoclave is quick, but most plastics used in SUDs can not survive the temperature. Thus, a number of new methods are being introduced on the market. To date, this program has studied the effects of five: EtO, peracetic acid + peroxide (Steris) , high temp formaldehyde, (Chemiclave), low temp peroxide gas plasma - (Sterrad) , and low temp peracetic acid gas plasma (Abtox). Tensile strength testing has shown that silicone elastomer is unaffected, whereas the strength of nylon, polyethyelene and latex was reduced by some of the methods. Depending on the formulation the strength of polyurethane either increased or decreased. The results demonstrate that the effect of sterilization depends on the method and the materials used in the device.

The Effect of Repeated Ethylene Oxide Sterilization on the Mechanical Strength of Synthetic Absorbable Sutures T.O. Woods[1], S.A. Brown[1], K. Merritt[2], & V.M. Hitchins[2]. [1]*Division of Mechanics & Materials Science,* [2]*Division of Life Sciences, CDRH, FDA, Rockville, MD 20850*

Sutures that are opened but not used are commonly reprocessed for reuse, though they are labeled for single use. The effect of repeated ethylene oxide (EO) sterilization on the knot strength of three types of absorbable sutures was tested. Suture inner packs were repacked and EO sterilized using a clinical protocol. Mean knot strength was measured out of package and after 1 and 2 Re-EO cycles. As is true for other devices, it is not possible to make general conclusions. Suture strength was not affected for some sutures; others increased or decreased in strength. Seals on some inner packs were destroyed during reprocessing, exposing the absorbable sutures to ambient humidity. While seal loss might not cause an initial strength loss, exposure to increased humidity for an extended time will cause suture degradation and loss of strength.

The Effect of Reprocessing on Single Use Electrophysiology Catheters T.O. Woods[1], S.A. Brown[1], K. Merritt[2], & V.M. Hitchins[2]. [1]*Division of Mechanics & Materials Science,* [2]*Division of Life Sciences, CDRH, FDA, Rockville, MD 20850*

Electrophysiology catheters (EPs) are one of the single use devices that are most often reported to be reprocessed and reused. Once it has been established that a used device can be cleaned and resterilized, it is necessary to show that its mechanical behavior has not been adversely affected. Torque and trackability, two clinically relevant mechanical properties of EPs, will be determined for a solid and hollow configuration of one model of EP catheter. The two types reflect a manufacturing change that was made without a change in model name. The two properties will be determined for new, unused catheters; for catheters after use in a single patient; and for used catheters subjected to a number of cycles of

ethylene oxide sterilization, simulated reuse and reprocessing cycles. Results for the two catheter types will be compared.

Reprocessing Single Use Biopsy Forceps for Reuse K.Merritt, V.M. Hitchins, S.A. Brown, T.O. Woods *Division of Life Sciences, Division of Mechanics and Material Science, CDRH, FDA, Rockville MD 20852*

Economic considerations in the delivery of health care are enticing some facilities to reuse single use devices. Biopsy forceps, used together with an endoscope in gastrointestinal procedures, are among the devices that some entities are reprocessing. If these forceps are to be reused on another patient, they must be adequately cleaned and sterilized. We have been examining 3 types of single use GI biopsy forceps. These have an external polymer sheath covering the spring that operates either jaws or a snare. The snares have an open lumen. The jaw forceps appear sealed but actually there is an open lumen. Cleaning of these devices with a sequence of bleach, ultrasonic bath with detergent and enzyme, and water rinse appears to remove residual debris. However, drying the lumens of these devices is very difficult. Residual water may decrease the effectiveness of sterilization.